In the Claims:

The following is a complete listing of the claims, intended to replace any claims previously set forth in this matter. Please amend the claims as shown. New claims 295-300 are added.

Claims 1-249 (CANCELLED).

250. (Currently Amended) A proprietary ~~new~~ method of use for~~, or characteristic of,~~ a product of manufacture or device, wherein the ~~identity of~~ the ~~new~~ use ~~or useful characteristic~~ was ~~derived~~ established according to the steps comprising:

accessing one or more data sources, wherein at least one data source comprises adverse event data;

analyzing and comparing adverse event data associated with a product of manufacture or device, with at least one previously-known adverse event associated with the product or device;

identifying at least one ~~new~~ novel essential adverse event associated with the product or device from the adverse event data, and then responsive to ~~identification~~ identifying of the essential novel adverse event, identifying the at least one ~~new characteristic of, or~~ novel method of use for~~,~~ the product or device;

documenting inventorship of the at least one ~~new characteristic of, or~~ novel method of use for~~,~~ the product or device; and

creating a database of proprietary essential adverse event information ~~database which stores~~, the database storing data regarding the at least one ~~new characteristic of, or use~~ novel essential adverse event, wherein the database comprises at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication.

251. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 250, wherein the steps of establishing the use further ~~comprising~~ comprise determining value of commercializing the at least one new ~~characteristic or~~ use determined from the at least one identified essential adverse event.

252. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 251, wherein the steps of establishing the use further ~~comprising~~ comprise commercializing the at least one ~~new~~ novel use ~~or characteristic~~.

253. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 252, wherein the steps of establishing the use, the commercializing step further ~~comprising~~ comprises generating information for incorporation into documents for selling, leasing or licensing the newly identified product information.

254. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 252, wherein the product is commercially available at the time of the analyzing step.

255. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim ~~253~~ 252, wherein the steps of establishing the use, commercializing further comprises formatting the data relating to at least one ~~new~~ novel adverse event associated with exposure to, or use of the product or device, or documenting same, such that a manufacturer or distributor of the product or device must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one ~~new~~ novel adverse event associated with exposure to or use of the product or device.

256. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 250, wherein the product or device is commercially available at the time of the analyzing step, and wherein in the steps of establishing the use, the at least one data source comprises information relating to patents and patent applications.

257. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 250, wherein the product or device is commercially available at the time of the analyzing step, and wherein in the steps of establishing the use, the at least one data source comprises information relating to raw commercial or sales data.

258. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 252, wherein the steps of establishing the use, the at least one adverse event comprises a drug interaction.

259. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 258, wherein the steps of establishing the use, the at least one data source comprises information relating to raw commercial or sales data.

260. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 250, wherein the steps of establishing the use of the essential adverse event data ~~is~~ are proprietary.

261. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 250, wherein the product is medical.

262. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 252, wherein the product is medical.

263. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 262, wherein the medical product is a generic drug.

264. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 250, wherein the product is non-medical.

265. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 252, wherein the product is non-medical.

266. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 250, wherein the device is medical.

267. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 252, wherein the device is medical.

268. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 250, wherein the device is non-medical.

269. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 252, wherein the device is non-medical.

270. (Currently Amended) A proprietary kit containing a product or device, and labeling notifying a user of at least one ~~new~~ novel essential adverse event for the product or device, wherein the kit is used in accordance with the proprietary ~~new~~ method of use ~~or characteristic~~ of claim 250.

271. (Currently Amended) A proprietary kit containing a product or device, and labeling notifying a user of at least one ~~new~~ novel essential adverse event for the product or device, wherein the kit is ~~created~~ used in accordance with the proprietary ~~new~~ method of use ~~or characteristic~~ of claim 259.

272. (Currently Amended) The proprietary ~~new~~ method of use ~~or characteristic~~ of claim 250, ~~further comprising identifying~~ wherein the ~~new~~ novel method of use ~~as~~ is a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

273. (Currently Amended) The proprietary ~~new~~ method of use ~~or characteristic~~ of claim 253, ~~further comprising identifying~~ wherein the ~~new~~ novel method of use ~~as~~ is a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

274. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 250, wherein the at least one adverse event is a drug interaction.

275. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 274, wherein the ~~drug interaction pertains to efficacy of a drug~~ product or device is commercially available at the time of the analyzing step.

276. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 275, wherein the ~~new~~ proprietary method of use comprises a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to, or use of, the product or device.

277. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 275, wherein at least one data source comprises information relating to raw commercial or sales data.

278. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 277 275, wherein at least one ~~new~~ novel adverse event is other than a chronic immune mediated disorder.

279. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim ~~278~~ 277, the steps further comprising determining value of commercializing the at

least one ~~new~~ proprietary method of ~~characteristic or~~ use determined from the at least one identified essential adverse event.

280. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim ~~279~~ 278, the steps further comprising commercializing the at least one ~~new~~ proprietary method of use ~~or characteristic~~ and the product or device is commercially available, wherein commercializing comprises formatting the data relating to at least one novel adverse event associated with exposure to, or use of the product or device, or documenting same, such that a manufacturer or distributor of the product or device must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one novel adverse event associated with exposure to or use of the product or device.

281. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 250, wherein at least one ~~new~~ novel essential adverse event comprises ~~an~~ a drug interaction, wherein at least one data source comprises information relating to patents and patent applications, and wherein at least one data source comprises information relating to raw commercial or sales data.

282. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 252, wherein at least one ~~new~~ novel essential adverse event comprises ~~an~~ a drug interaction, wherein at least one data source comprises information relating to patents and patent applications, and wherein at least one data source comprises information relating to raw commercial or sales data.

283. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 250, wherein the at least one adverse event data source comprises information regarding product post-exposure adverse event data, which is recorded in selected time increments, ranging from less than one hour to more than ten years.

284. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 250, wherein the at least one adverse event data source comprises information regarding amount of use of the product or device or duration of exposure to the product or device by subjects.

285. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of 250, wherein the at least one ~~new~~ novel method of use of the product or device is a restricted use in at least one population subgroup, when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device and the ~~new~~ novel adverse event is one other than a chronic immune mediated disorder.

286. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of 252, wherein the at least one ~~new~~ novel method of use of the product or device is a restricted use in at least one population subgroup, when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device and the ~~new~~ novel adverse event is one other than a chronic immune mediated disorder.

287. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 250, wherein the product or device is commercially available, the steps further comprising identifying the ~~new~~ novel method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

288. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 251, wherein the product or device is commercially available, the steps further comprising identifying the ~~new~~ novel method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

289. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 252, wherein the product or device is commercially available, the steps further comprising identifying the ~~new~~ novel method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

290. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 259, wherein the product or device is commercially available, the steps further comprising identifying the ~~new~~ novel method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

291. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 250, the steps further comprising documenting date of inventorship.

292. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 250, wherein at least one adverse event data source comprises raw data from a plurality of different adverse events.

293. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 250, wherein the product or device is commercially available, and the ~~new~~ novel method of use is further identified as comprising restricting exposure of the product or device to one of the high risk associated groups selected from the group consisting of high or low temperatures, chemicals, surfaces, pressures, electricity and sparks; or contact of the product or device with one of the group selected from the group consisting of skin, eyes, ears, respiratory surfaces, gastrointestinal surfaces and mucous membranes of the consumer; or exposure to a subpopulation group selected from the group consisting of children, pregnant women, consumers with specific allergies or medical conditions and animals; or exposure to a subpopulation defined by at least one consumer-identifying characteristic selected from the group consisting of sex, weight, age, race, genetic characteristics, medical condition, pregnancy status, presence of allergies, and use of ~~medicines~~ drugs, diet, tobacco, alcohol, or medical devices.

294. (Currently Amended) The ~~new~~ proprietary method of use ~~or characteristic~~ of claim 250, ~~where~~ wherein at least one database of ~~new~~ essential adverse event information ~~database~~ is computerized.

295. (New) The proprietary method of use of claim 250, wherein the steps of establishing the use further comprises accessing one or more data sources, wherein at least one data source comprises human adverse event data.

296. (New) The proprietary method of use of claim 250, wherein the steps of establishing the use further comprises utilizing least one controlled clinical trial and or epidemiological study to discover at least one novel adverse event.

297. (New) The proprietary method of use of claim 250, wherein the step of establishing the adverse event is one other than an abnormal laboratory value.

298. (New) The proprietary method of use of claim 250, wherein the novel use is one other than a new dosing regimen.

299. (New) The proprietary method of use of claim 250, wherein the novel use further comprises providing novel printed product safety information in connection with product packaging.

300. (New) The proprietary method of use of claim 250, wherein the novel use further comprises providing novel printed product warning information in connection with product packaging.